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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/654,761

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Dennis Ausiello

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/654,761	Applicant(s) AUSIELLO ET AL.	
	Examiner ELIZABETH R. MACNEILL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-21, 24, 27, 32, 34-36 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-21, 24, 27, 32, 34-36 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,12,17-19,24,27,32, 34,35, and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini et al (WO 01/12157) in view of Cheikh (US 5,660,846).

Santini teaches and implantable (Page 5 line 19) medical device for controlled delivery of a medical substance having a substrate (130) with a plurality of reservoirs (180), a release system (medical substance), with discrete reservoir caps (120b), which are disintegrated by means of electrothermal ablation (via integrated resistors 140b). See Fig 5, described at page 39. Santini discusses the electrothermal ablation of the reservoirs at page 2 lines 15-20, page 10 lines 14-23, and also page 13 (list not exclusive). The reservoir cap may be metal (Col 12 line 15) such as copper, gold, etc. Santini does not disclose the delivery of parathyroid hormone, but does teach a generic hormone (page 9 line 4).

Cheikh teaches the delivery of a parathyroid hormone from an implantable device (Col 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose the parathyroid hormone to deliver from the device of Santini in order to provide appropriate medical treatment to the patient.

As to claim 17, Santini teaches that it is known to provide hundreds or thousands of reservoirs (page 1 line 21).

As to claim 18, see page 7 line 12.

As to claim 19, see page 6 line 30, the molecules may be in a solid.

As to claims 24 and 34 see page 14, lines 12-25 and Fig 5, Fig 9C.

As to claim 27, see page 14 line 14.

As to claim 35, see Fig 6D, page 41 lines 12-22.

As to claims 38-40, see page 2 lines 15-20, page 10 lines 14-23, and also page 13

As to claim 41, see Col 12 line 15 and Col 6 line 10

As to claim 42, see page 12 which teaches a platinum cap (line 15) and that the caps may be layered (line 23). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form a platinum cap with a titanium layer as suggested to increase the strength of the cap before rupture.

3. Claims 2-10 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Cheikh as applied above, and further in view of Rubin, et al., "The Potential of Parathyroid Hormone as a Therapy for Osteoporosis," Int. J. Fertil. 47(3): 103-15 (2002) (cited by applicants; hereinafter "Rubin").

Santini and Cheikh teach the device and method as above, but fail to teach the details of the parathyroid treatment.

Rubin suggests the use of parathyroid hormone to treat osteoporosis. Rubin discusses dosage, length of therapy and the use of bone resorption inhibitors as well. It would have been obvious to one of ordinary skill in the art to modify the system disclosed by

Santini and Cheikh, by including parathyroid hormone as the release system in order to provide therapy for those suffering from osteoporosis.

4. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Cheikh, further in view of U.S. Patent No. 6,011,011 to Hageman.

Santini and Cheikh disclose the claimed invention as shown above except for an excipient of polyethylene glycol. Hageman teaches the use of polyethylene glycol as an excipient with parathyroid hormone. See col. 3, line 28 through col. 4, line 12. It would have been obvious to one of ordinary skill in the art to modify the invention of Santini and Cheikh by including polyethylene glycol as an excipient in order to provide a sustained or prolonged release of the hormone.

Response to Arguments

Applicant's arguments filed 24 September 2007 have been fully considered but they are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767